



Inspection Report

Lovelace Respiratory Research Institute
2425 Ridgecrest S E
Albuquerque, NM 87108

Customer ID: **1072**

Certificate: **85-R-0003**

Site: 001

LOVELACE RESPIRATORY RESEARCH INSTITUTE

Type: ROUTINE INSPECTION

Date: Jul-19-2016

2.31 (c) (7)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

***Changes regarding the care and use of animals in ongoing activities are not always approved by the IACUC before the changes occur. On July 8, 2016, a Sinclair pig underwent 3 CSF collections during a training session. Although an amendment had been submitted, the IACUC approved training protocol, FY15-078 Training Protocol for Procedures in Laboratory Swine, did not include approval for CSF collection. The amendment to include CSF collection was not approved until after this incident.

Unapproved significant changes to the protocol could result in unanticipated pain and distress, and put the animal's welfare at risk. Any significant changes to the approved protocol must be reviewed and approved by the IACUC prior to implementing the changes.

Correct by 7/21/16.

2.31 (d) (5)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

***The IACUC did not conduct appropriate reviews of the animal activities for protocol FY15-127 to ensure that the study personnel were following the approved protocol. The animal use activity involved non-human primates.

The protocol states in several sections humane endpoints/criteria for unplanned euthanasia include respiratory distress (labored breathing, dyspnea, gasping/agonal breathing), loss of appetite and lethargy. Additionally, the protocol states if complications are noted, the clinical veterinarian is to be consulted regarding decisions for humane euthanasia.

Clinical observations for animal RA1950 noted the following:

4/19/16: lethargic, labored respiration, no appetite, slight labored breathing

4/20/16: rapid respiration, hypoactive, no/poor appetite

4/21/16: rapid respiration, hypoactive, no/poor appetite

Electronic correspondence (4/19/16-4/21/16) between study personnel regarding animal RA1950

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confirmed the clinic observations of rapid respiration, lethargy, decrease in appetite (the animal would no longer eat its biscuits), hypoactive and reluctance to move until stimulated. On 4/22/16 the animal was found expired on its enclosure floor.

At no time after the notation of clinical observations, which met approved humane endpoints, was the clinical veterinarian notified or consulted as required by the approved protocol. The IACUC is required to conduct continuing review of all animal activities in order to ensure that they are conducted in compliance with the approved protocol and to ensure that the animals do not experience any undue pain and suffering.

The IACUC must continue reviewing all activities involving animals, in order to ensure that all animal activities are conducted as stated in the approved protocol and in compliance with these regulations.

To be corrected by 7/21/16

***The IACUC did not conduct appropriate reviews of the animal activities for protocol FY14-132 to ensure that the study personnel were following the approved IACUC protocol. The animal use activity involved non-human primates.

The IACUC protocol states that the groups of animals will receive one of the following: Drug A; Drug A + B; or Drug A + C.

According to the study protocol (not reviewed and approved by the IACUC) and animal dosing records, the group 3 animals received Drug A + Drug B + Drug C. This combination of drugs was not approved in the IACUC protocol prior to dosing. An amendment has since been approved by the IACUC to include new dosing regimens. The IACUC is required to conduct continuing review of all animal activities in order to ensure that they are conducted in compliance with the approved protocol and to ensure that the animals do not experience any undue pain and suffering.

The IACUC must continue reviewing all activities involving animals, in order to ensure that all animal activities are conducted as stated in the approved protocol and in compliance with these regulations.

Correct by 7/21/16

2.38 (f) (1) REPEAT

MISCELLANEOUS.

***Handling of all animals was not done in a manner that did not cause trauma. On March 11, 2016, six guinea pigs expired during transportation for study related activities. The animals were held in a rat microisolator enclosure (used for transportation), for approximately 45-60 minutes before initiating transport to the exposure room. Immediately upon leaving the animal room, study personnel noted the animals had expired. An IACUC investigation revealed three contributing factors in this incident: the density of guinea pigs in the enclosure, duration they were held in the enclosure, microisolator filter top was wet (may contribute to decreased air exchange within the enclosure).

The facility has addressed the identified contributing factors, revised relevant SOP s and retrained staff.

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Handling of all animals shall be done as expeditiously and carefully as possible in a manner that does not cause trauma, behavioral stress, physical harm, or unnecessary discomfort.

This was a focused inspection on facility records.

Inspection was conducted on 7/19/16 with the IACUC chair, Attending Veterinarian and the Director of Scientific Support Services, along with APHIS personnel to include Dr. Aaron Rhyner and Dr. Tanya Tims.

Exit briefing was conducted on 7/20/16 with facility personnel along with APHIS personnel to include Dr. Aaron Rhyner and Dr. Tanya Tims.

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